Sulzer Intrapeutics, Inc. IntraCoil® Self-Expanding Peripheral Stent

CAUTION: Rx Only

INSTRUCTIONS FOR USE

TABLE OF CONTENTS

1 DEVICE DESCRIPTION

The IntraCoil® Self-Expanding Peripheral Stent includes

- A 40 mm nitinol coil stent with evenly placed coils in the open configuration.
- A flexible over-the-wire delivery catheter with radiopaque marker bands that aid in accurate stent placement. The stent is wound onto the distal end of the delivery catheter in a reduced diameter and held in place by the release mechanism at the proximal end. Retracting the white and black knobs releases the proximal and distal stent ends respectively.

The stent is MRI safe and does not interfere with, nor is affected by, the operation of an MRI device (Teitelbaum, et.al., 1988).

2 INDICATIONS FOR USE

The IntraCoil® Self-expanding Peripheral Stent is indicated for use following abrupt closure or suboptimal percutaneous transluminal angioplasty (PTA) of superficial femoral or popliteal artery occlusions ≤ 12 cm or stenotic lesions ≤ 15 cm in length. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of ≥ 50% residual stenosis or a Grade C or greater dissection.

3 CONTRAINDICATIONS

The IntraCoil® Self-Expanding Peripheral Stent is contraindicated for use in patients who have a lesion that cannot be crossed with a wire and/or balloon catheter.

4 WARNINGS/ PRECAUTIONS

4.1 Warnings

- The stent is intended for use by physicians who have received appropriate training in interventional techniques and placement of intravascular stents.
- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated should be treated with caution.

4.2 Stent Handling - Precautions

- The system is provided STERILE for one use only and should be used by the "Use Before Date" printed on the package. Do Not Resterilize.
- Carefully inspect the sterile package and device prior to use to verify that neither has been damaged during shipment.

4.3 Stent Placement - Precautions

- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to the stent or vessel.
- The system is not intended for repositioning or recapturing.
- Caution should be used when crossing a deployed stent with any adjunct device.

5 ADVERSE EVENTS

A total of 357 patients were enrolled in a multi-center clinical trial as summarized in Table 2. Randomized patients from the U.S. Randomized Trial form the basis of the observed adverse events in Table 3.

Table 2. Patient Enrollment in Clinical Studies

	IntraCoil Stent	PTA	Patient Totals
U.S. Randomized Trial			
Roll-in patients	91	--	91
Randomized patients	135	131	266
PATIENT TOTALS	**226**	**131**	**357**

5.1 Observed Adverse Events

A total of eighteen deaths have occurred in the U.S. randomized trial (five stent patients, thirteen PTA patients). All five stent patients died after discharge (52, 693, 738, 757 and 789 days post-procedure). Causes of death were multiple system failure, colon cancer, unknown, lung cancer and cardiac arrest. Of the thirteen PTA deaths, one occurred in-hospital (due to renal failure and pulmonary edema), and twelve after discharge (34, 37, 252, 390, 505, 652, 690, 699, 762, 839, 840, and 962 days post-procedure). Causes of death for the twelve late cases were renal failure, septicemia, cardiac arrest (2), cardiogenic shock with severe CAD, lung cancer (2), respiratory failure, bleeding following surgery, traumatic head injury and unknown (2).

There have been nine deaths in the Roll-in group; 49, 84, 324, 581, 607, 645, 875, 883, and 1026 days post-procedure. Causes of death were congestive heart failure, hepatic failure, multiple system failure, colon cancer, unknown, stroke, multiple sclerosis, ischemic cardiomyopathy, and respiratory failure. The only other MACE event within the first nine months was target lesion revascularization (TLR-free at 270 days, 76.9% [73.9%, 89.1%]).

Delivery failures occurred in 15 patients (5.6%) in the U.S. randomized trial (5 stent patients, 10 PTA patients). The five delivery catheter failures in the stent group were due to handle failures in early lots (2) and deployment difficulties (3) due to early manufacturing methods. Delivery failures in the PTA group included crossover to stent (9) and to another device (1).

5.2 Potential Adverse Events

Adverse events (in alphabetical order) that may be associated with the use of vascular stents in peripheral vessels (in addition to those listed in Table 3):

- AV Fistula Formation
- Dissection
- Drug reactions to antiplatelet agents/ contrast medium
- Hematoma
- Hypotension/hypertension
- Infection and/or pain at the access site
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stroke/cerebrovascular accident
- Vessel perforation or rupture

Table 3. Adverse Events during the First 9 Months
%[± 95% Confidence Interval] (Number) All randomized U.S. patients (n=266)

Adverse Event	IntraCoil Stent (n=135)	PTA (n=131)	Difference [95% CI]
ANY MACE Event	15.6% [9.9%,22.8%] (21)	16.0% [10.2%,23.5%] (21)	-0.5% [-9.2%,8.3]
Early (in-hospital)	0.7% [0.02%,4.1%] (1)	2.3% [0.5%,6.5%] (3)	-1.5% [-4.5%,1.4%]
Out–of-hospital	15.6% [9.9%,22.8%] (21)	13.7% [8.4%,20.8%] (18)	-1.8% [-6.7%,10.3%]
Death Total	0.7% [0.02%,4.1%] (1)	3.1% [0.8%,7.6%] (4)	-2.3% [-5.6%,1.0%]
Early (in-hospital)	0% [0.0%,2.7%] (0)	0.8% [0.02%,4.2%] (1)	-0.8% [-2.3%,0.7%]
Out–of-hospital	0.7% [0.02%,4.1%] (1)	2.3% [0.5%,6.5%] (3)	-1.5% [-4.5%,1.4%]
Q-wave MI Total	0% [0.0%,2.7%] (0)	0% [0.0%,2.8%] (0)	0.0% [-,-]
Early (in-hospital)	0% [0.0%,2.7%] (0)	0% [0.0%,2.8%] (0)	0.0% [-,-]
Out–of-hospital	0% [0.0%,2.7%] (0)	0% [0.0%,2.8%] (0)	0.0% [-,-]
Non-Q-wave MI Total	2.2% [0.5%,6.4%] (3)	0% [0.0%,2.8%] (0)	2.2% [-0.3,4.7%]
Early (in-hospital)	0% [0.0%,2.7%] (0)	0% [0.0%,2.8%] (0)	0.0% [-,-]
Out–of-hospital	2.2% [0.5%,6.4%] (3)	0% [0.0%,2.8%] (0)	2.2% [-0.3,4.7%]
Amputation Total	0% [0.0%,2.7%] (0)	0.8% [0.02%,4.2%] (1)	-0.8% [-2.3%,0.7%]
Early (in-hospital)	0% [0.0%,2.7%] (0)	0.8% [0.02%,4.2%] (1)	-0.8% [-2.3%,0.7%]
Out–of-hospital	0% [0.0%,2.7%] (0)	0% [0.0%,2.8%] (0)	0.0% [-,-]
Abrupt Closure Total	0% [0.0%,2.7%] (0)	2.3% [0.5%,6.5%] (3)	-2.3% [-4.9%,0.3%]
Early (in-hospital)	0% [0.0%,2.7%] (0)	1.5% [0.2%,5.4%] (2)	-1.5% [-3.6%,0.6%]
Out–of-hospital	0% [0.0%,2.7%] (0)	0.8% [0.02%,4.2%] (1)	-0.8% [-2.3%,0.7%]
Subacute Closure Total	0.7% [0.02%,4.1%] (1)	2.3% [0.5%,6.5%] (3)	-1.5% [-4.5%,1.4%]
Early (in-hospital)	0.7% [0.02%,4.1%] (1)	1.5% [0.2%,5.4%] (2)	-0.8% [-3.3%,1.8%]
Out–of-hospital	0% [0.0%,2.7%] (0)	0.8% [0.02%,4.2%] (1)	-0.8% [-2.3%,0.7%]
Distal Embolization Total	0% [0.0%,2.7%] (0)	0.8% [0.02%,4.2%] (1)	-0.8% [-2.3%,0.7%]
Major Bleeding Complications	0.7% [0.02%,4.1%] (1)	0.8% [0.02%,4.2%] (1)	0.0% [-2.1%,2.1%]
Major Vascular Complications	3.7% [1.2%,8.4%] (5)	4.6% [1.7%,9.7%] (6)	-0.9% [-5.7%,3.9%]
Renal Failure	0% [0.0%,2.7%] (0)	2.3% [0.5%,6.5%] (3)	-2.3% [-4.9%,0.3%]

ANY MACE Event includes death, peri-procedure Q Wave MI, target lesion revascularization (TLR)
Early (in-hospital) refers to events during the hospitalization for the initial trial treatment. In cases where a patient experienced both an in-hospital event and an out-of-hospital event, they are counted once in each group, but only once in the event total. Hence, the sum of the in-hospital and the out-of-hospital event rate may not equal the total event rate.
Stent Delivery Failures: unable to deliver stent, stent misplacement
Amputation: any requirement for amputation transmetatarsal or higher that was unanticipated before the procedure.
Abrupt Closure: slow or reduced flow due to mechanical dissection (of grade E or higher), thrombus, or severe microvascular spasm that resulted in additional unplanned stent use or surgery.
Subacute Closure: target lesion site occlusion within 30 days of the procedure.
Distal Embolization: migration of a filling defect or thrombus to a distal vessel.
Renal Failure: decrement in renal function related to the index procedure requiring temporary or chronic dialysis; or repeat hospitalization for worsening renal function attributable to the index procedure.

6 CLINICAL STUDIES

A total of 327 patients were treated at 23 U.S. investigational sites in the U.S. Randomized Trial (Table 2). The U.S. Randomized Trial is summarized below.

Primary Endpoint: The primary endpoints were MACE at nine months and angiographic restenosis of the target vessel at nine months. MACE was defined as a composite of death within 30 days, peri-procedural Q Wave MI, and clinically driven target lesion revascularization (TLR) within nine months. Angiographic restenosis was defined as ≥ 50% restenosis. An independent clinical events committee adjudicated all of the major clinical endpoints.

Patients Studied: Eligible patients were candidates for percutaneous transluminal angioplasty (PTA), with symptomatic leg ischemia, requiring treatment of a single superficial femoral/popliteal vessel with a occluded lesion length ≤ 12 cm or stenotic lesion length ≤ 15 cm.

Methods: Patients were prospectively randomized to treatment with the IntraCoil stent or PTA. The patients underwent balloon angioplasty with an appropriate balloon diameter matching the reference vessel diameter. The goal was a residual stenosis of <50% in both the stent and PTA groups.

Patients in the PTA arm were to receive secondary treatment only if 1) acute results indicated abrupt closure or impending closure due to severe recoil or extensive dissection, not correctable despite repeated balloon inflations to high pressure, longer inflation, or larger balloon size (if appropriate) or 2) during follow-up there was angiographically defined restenosis or dissection that was limb threatening.

Clinical follow-up visits were conducted at six months, nine months and one year. Nine-month angiographic follow-up was requested from the first 250 patients. Antiplatelet therapy included aspirin 325-mg/day indefinitely and Ticlid-250 mg/twice daily for one month. Anticoagulation therapy was at the discretion of the physician.

Results: The study was stopped early due to slow enrollment. Baseline characteristics were similar for the two treatment groups in the randomized trial. All patients were included in the intent-to-treat efficacy analysis. No statistical difference was found for nine month MACE between the IntraCoil stent and PTA groups. Table 4 shows the principal effectiveness and safety results.

Table 4. Principal Effectiveness and Safety Results
All Patients in the Stent Group and PTA Group (n=266 Patients, 361 Lesions)

Efficacy Measures	B. IntraCoil Stent (n=135 patients, 181 lesions)	C. PTA (n=131 patients, 180 lesions)	Difference B:C [95% CI]
Acute angiographic success	85.4% (152/178)	82.2% (143/174)	3.2% [-4.5%,10.9%]
Acute (30 day) procedure success	80.6% (108/134)	77.1% (101/131)	3.5%[-6.3%,13.3%]
Device success	91.8% (117/131)	89.3% (117/131)	2.5%[-4.6%,9.5%]
Change of ABI (from baseline to 9 mos.)	0.19 ± 0.20 (83)	0.08 ± 0.19 (64)	0.10 [0.04,0.16]
Range (min, max)	(-0.43, 0.56)	(-0.25, 0.52)	
9-mo follow-up in-lesion binary restenosis rate	41.2% (40/97)	33.7% (31/92)	7.5%[-6.2%,21.3%]
TLR-free at 9 months (K-M)	85.7% [79.9%, 91.5%]	83.9% [78.0%, 89.7%]	1.8%[-6.4%,10.0%]
TVR-free at 9 months (K-M)	81.1% [73.9%, 88.4%]	83.1% [76.1%, 90.2%]	-2.0%[-12.1%,8.1%]
MACE-free at 9 months (K-M)	80.5% [73.2%, 87.8%]	81.2% [73.9%, 88.4%]	-0.7%[-11.0%,9.6%]
Thrombolysis-free at 9 mos. (K-M)	96.8% [93.5%,100.0%]	100.0%	-3.2%[-6.5%,0.2%]
Safety Measures			
In-Hospital MACE	0.7% (1/135)	2.3% (3/131)	-1.5%[-4.5%,1.4%]
Major Complications at 30 days	1.5% (2/135)	8.4% (11/131)	-6.9%[-12.1%,-1.7%]
Major bleeding complications	0.7% (1/135)	0.8% (1/131)	0.0%[-2.1%,2.1%]
Major vascular complications	3.7% (5/135)	4.6% (6/131)	-0.9%[-5.7%,3.9%]
Amputation to 9 months	0.0% (0/135)	0.8% (1/131)	0.8%[-2.3%,0.7%]
Abrupt closure	0.0% (0/135)	2.3% (3/131)	-2.3%[-4.9%,0.3%]
Subacute closure	0.7% (1/135)	2.3% (3/131)	-1.5%[-4.5%,1.4%]
Distal embolization	0.0% (0/135)	0.8% (1/131)	-0.8%[-2.3%,0.7%]
Renal Failure	0.0% (0/135)	2.3% (3/131)	-2.3%[-4.9%,0.3%]

Numbers are % (counts/sample size) or mean ± standard deviation. **CI** is Confidence Interval.
Acute Angiographic Success: achievement of a final residual stenosis of <50% and ≥20% improvement in diameter stenosis by QA.
Acute Procedural Success: achievement of a final residual diameter stenosis of <50% and ≥20% improvement in diameter stenosis by QA without death, stroke, Q wave MI, bleeding requiring >2 units transfusion, or any other complication which was device- or procedure- related and which required an unanticipated interention or surgical procedure within the first 30 days after treatment. If no in-stent measurements were available, in-lesion measurements were used, and if no QA was available, visual estimates were used.
Device Success: achievement of a final residual diameter stenosis of <50% by QA with successful delivery of the assigned device at least once and freedom from stent embolization, from stent migration, and from use of a device outside the assigned treatment strategy. If no in-stent measurements were available, in-lesion measurements were used, and if no QA was available, visual estimates were used.
K-M: survival estimates by Kaplan-Meier method. Standard Error estimates by Greenwood formula.
TLR: target lesion revascularization. **TVR:** target vessel revascularization. **MACE:** death, peri-procedural Q wave MI, or target lesion revascularization. **In-Hospital:** prior to hospital discharge. **Out-of-Hospital:** after hospital discharge.
Amputation: any requirement for amputation transmetatarsal or higher that was unanticipated before the procedure.
Abrupt Closure: slow or reduced flow due to mechanical dissection (of grade E or higher), thrombus, or severe microvascular spasm that resulted in additional unplanned stent use or surgery.
Subacute Closure: target lesion site occlusion within 30 days of the procedure.
Distal Embolization: migration of a filling defect or thrombus to a distal vessel.
Renal Failure: decrement in renal function related to the index procedure requiring temporary or chronic dialysis; or repeat hospitalization for worsening renal function attributable to the index procedure.

Examination of the stent group indicated that in a large percentage of cases (31%, 69/226) the angioplasty result before placement of the stent was suboptimal (defined as ≥ 50% residual stenosis or a Grade C or greater dissection). This subgroup is representative of the use of the stent as secondary treatment after suboptimal PTA. An additional analysis was conducted to determine if the results of stenting after suboptimal PTA was equivalent to treatment with PTA only. Table 5 shows the principal effectiveness and safety results for this comparison. Figure 1 shows the primary endpoint, actuarial freedom from MACE at nine months.

Table 5. Principal Effectiveness and Safety Results
All Patients in the Stent after Suboptimal PTA Group and PTA Group (n=201 patients, 269 lesions)

Efficacy Measures	IntraCoil Suboptimal Group (n=70 patients, 89 lesions)	PTA (n=131 patients, 180 lesions)	Difference B:C [95% CI]
Acute angiographic success	83.0% (73/88)	82.2% (143/174)	0.8%[-8.9%,10.5%]
Acute (30 day) procedure success	81.4% (57/70)	77.1% (101/131)	4.3%[-7.3%,15.9%]
Device success	87.1% (61/79)	89.3% (117/131)	-2.2%[-11.6%,7.3%]
Change of ABI (from baseline to 9 mos.)	0.17 ± 0.18 (48)	0.08 ± 0.19 (64)	0.09 [0.02,0.16]
Range (min, max)	(-0.17, 0.56)	(-0.25, 0.52)	
9-mo follow-up in-lesion binary restenosis rate	39.1% (18/46)	33.7% (31/92)	5.4%[-11.7%,22.5%]
TLR-free at 9 months (K-M)	84.2% [76.2%, 92.2%]	83.9% [78.0%, 89.7%]	0.3%[-9.6%,10.2%]
TVR-free at 9 months (K-M)	77.4% [67.1%, 87.7%]	83.1% [76.1%, 90.2%]	-5.8%[-18.2%,6.7%]
MACE-free at 9 months (K-M)	77.4% [67.1%, 87.7%]	81.2% [73.9%, 88.4%]	-3.8%[-16.4%,8.8%]
Safety Measures			
In-Hospital MACE	0.0% (0/70)	2.3% (3/131)	-2.3%[-4.9%,0.3%]
In and Out-of-Hosp. MACE to 30 days	0.0% (0/70)	2.3% (4/131)	-3.1%[-6.0%,-0.1%]
Major Complications at 30 days	2.9% (2/70)	8.4% (11/131)	-5.5%[-11.7%,0.6%]
Major bleeding complications	1.4% (1/70)	0.8% (1/131)	0.7%[-2.5%,3.8%]
Major vascular complications	2.9% (2/70)	4.6% (6/131)	-1.7%[-7.0%,3.6%]
Amputation to 9 months	1.4% (1/70)	0.8% (1/131)	0.7%[-2.5%,3.8%]
Abrupt closure	0.0% (0/70)	2.3% (3/131)	-2.3%[-4.9%,0.3%]
Subacute closure	0.0% (0/70)	2.3% (3/131)	-2.3%[-4.9%,0.3%]
Distal embolization	0.0% (0/70)	0.8% (1/131)	-0.8%[-2.3%,0.7%]
Renal Failure	0.0% (0/70)	2.3% (3/131)	-2.3%[-4.9%,0.3%]

Numbers are % (counts/sample size) or mean ± standard deviation. **CI** is Confidence Interval.

Acute Angiographic Success: achievement of a final residual stenosis of <50% and ≥20% improvement in diameter stenosis by QA.

Acute Procedural Success: achievement of a final residual diameter stenosis of <50% and ≥20% improvement in diameter stenosis by QA without death, stroke, Q wave MI, bleeding requiring >2 units transfusion, or any other complication which was device- or procedure- related and which required an unanticipated interention or surgical procedure within the first 30 days after treatment. If no in-stent measurements were available, in-lesion measurements were used, and if no QA was available, visual estimates were used.

Device Success: achievement of a final residual diameter stenosis of <50% by QA with successful delivery of the assigned device at least once and freedom from stent embolization, from stent migration, and from use of a device outside the assigned treatment strategy. If no in-stent measurements were available, in-lesion measurements were used, and if no QA was available, visual estimates were used.

K-M: survival estimates by Kaplan-Meier method. Standard Error estimates by Greenwood formula.

TLR: target lesion revascularization. **TVR:** target vessel revascularization. **MACE:** death, peri-procedural Q wave MI, or target lesion revascularization. **In-Hospital:** prior to hospital discharge. **Out-of-Hospital:** after hospital discharge.

Amputation: any requirement for amputation transmetatarsal or higher that was unanticipated before the procedure.

Abrupt Closure: slow or reduced flow due to mechanical dissection (of grade E or higher), thrombus, or severe microvascular spasm that resulted in additional unplanned stent use or surgery.

Subacute Closure: target lesion site occlusion within 30 days of the procedure.

Distal Embolization: migration of a filling defect or thrombus to a distal vessel.

Renal Failure: decrement in renal function related to the index procedure requiring temporary or chronic dialysis; or repeat hospitalization for worsening renal function attributable to the index procedure.

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the IntraCoil stent. In the U.S. Randomized Trial, the significant predictors of target lesion revascularization (TLR) were baseline ABI and pre-procedure reference vessel diameter (RVD). Larger RVD and higher baseline ABI were associated with lower occurrence of target lesion revascularization.

7.2 Specific Patient Populations

The safety and effectiveness of the IntraCoil stent has not been established for patients with any of the following characteristics:

- Patients allergic to nickel.
- Patients with diffuse disease or poor outflow distal to the identified lesions(s).
- Patients with poor aortoiliac or common femoral "inflow."
- Patients with unresolved vessel thrombus at the lesion site.
- Patients with targeted lesions in vessels with a reference diameter ≤ 3mm.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters), or laser angioplasty catheters, to treat in-stent stenosis has not been established.

INSERT KAPLAN-MEIER

8 OPERATOR'S INSTRUCTIONS

8.1 Initial Angioplasty

1. After local anesthesia is administered, the femoral artery is entered with a puncture needle and a sheath is inserted: 7 Fr for 4 mm and 5 mm stents, 8 Fr for 6 mm and 7 mm stents, and 9 Fr for 8 mm stents.
2. A 0.035" (0.89 mm) diameter or smaller guidewire is introduced into the artery through the sheath and should be advanced across the stenosis, followed by a diagnostic catheter for contrast injection.
3. An injection of contrast media through the sheath should be done in order to confirm the lesion length and diameter.
4. An angioplasty balloon catheter should be selected to correspond to the diameter of the artery proximal to the lesion.
5. Following dilation of the lesion, an arteriographic image should be recorded in order to determine the adequacy of the primary procedure.
6. The stent diameter should be up to 1 mm larger than the post dilation artery diameter or the same diameter as the balloon inflation diameter. **(NOTE: Appropriate sizing of the vessel is required to eliminate the possibility of migration.)** If a long lesion is treated two or more successive stents may be implanted. If multiple stents are used, deliver the most distal stent first.

8.2 Stent and Catheter System Preparation

1. Carefully inspect the device and package for damage; remove the device from the package.
2. Remove the protective stylet from the guidewire lumen at the distal tip of the catheter.
3. Flush through the guidewire lumen using sterile saline.

8.3 Stent Implantation

1. Use an exchange 0.035" (0.89 mm) diameter guidewire or smaller to remove the balloon.
2. Under fluoroscopy, advance the delivery catheter over the guidewire to the site of the dilated lesion.
3. To position the stent correctly across the lesion, use the two (2) radiopaque rings that mark the distal end of the stent and proximal end of the stent. Position the distal marker slightly past the most distal point of the lesion (Figure 3).

NOTE: Do not bend or kink catheter during deployment.

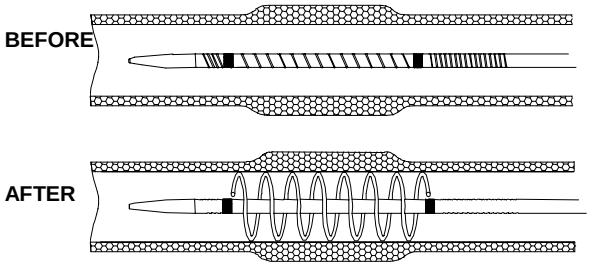

Figure 3. Positioning and Releasing the Stent

4. Remove the protective black safety sleeve from the handle.
5. To release the proximal end of the stent from the delivery catheter, slowly retract the white knob until it reaches the stopper releasing the proximal end of the stent.
6. To release the distal end of the stent from the delivery catheter, slowly retract the black knob until it reaches the white knob.

NOTE: During deployment the stent shortens 30 to 40 percent from the proximal end towards the distal end (Figure 3). In an appropriately sized vessel, it will deploy between the radiopaque rings.

7. Remove the delivery catheter cautiously and slowly under fluoroscopy, being careful not to catch the stent loops. Turn the catheter counterclockwise to facilitate removal.

NOTE: After placement of the stent, if expansion is not complete, a balloon (**not larger than the stent size**) can be cautiously placed inside the stent lumen for further expansion.

8. Verify stent patency and position
9. Administer an anticoagulation therapy that is standard for your hospital.

8.4 Tandem Stenting

1. If the lesion length requires using multiple stents always implant the most distal stent first by following the procedure described above.
2. When placing the subsequent stent, position the distal radiopaque marker adjacent to the proximal end of the first stent as shown in Figure 4.
3. Deploy the new stent and remove delivery catheter as described previously.

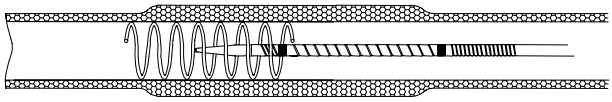

Figure 4. First Stent Placement for Tandem Stenting

9 HOW SUPPLIED

STERILE: This device is EtO sterilized. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

CONTENTS: One (1) IntraCoil Self-expanding Peripheral Stent on delivery catheter
One (1) Instructions for Use Manual

10 REFERENCES

Teitelbaum GP, Bradley Jr. WG and Klein B (1988). MR Imaging Artifacts, Ferromagnetism, and Magnetic Torque of Intravascular Filters, Stents, and Coils, **Radiology**, 166:657-664.

DISCLAIMER OF WARRANTY

IntraTherapeutics, Inc. has taken reasonable care in the design and manufacture of this product. Other than this representation, there are **NO EXPRESS OR IMPLIED WARRANTIES INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE**. IntraTherapeutics, Inc. shall not be liable for any incidental or consequential damages other than as expressly provided by specific law. No person has the authority to make any representation or warranty other than as set forth in this paragraph.

IntraTherapeutics, Inc. • 651 Campus Drive • St. Paul, MN 55112 • USA

Customer Service: 651-697-4840 • Fax 651-697- 4841, Toll Free in USA 877-697-4840 • Fax 877-697-4841